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SWANSON & BRATSCHUN, L.L.C
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/719,540	HALE ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/9/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-9 and 12-24* is/are pending in the application.

4a) Of the above claim(s) *21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-9, 12-20, and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 5-9, and 12-24 are pending. Applicants previously cancelled claims 2-4 and 10-11. Claims 21-23 are withdrawn from consideration because these were drawn to non-elected subject matter. **Claims 1, 5-9, 12-20, and 24 are under consideration** in the instant office action. Receipt and consideration of Applicants' unamended claims and remarks/arguments submitted on November 09, 2009 are acknowledged.

Election/Restrictions

The restriction of record is maintained at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-9, 12-15, and 24 **remain rejected** under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) in view of Drug Information Handbook, 2nd edition (Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 554-555) ("DIH") for the reasons of record set forth on pages 11-12 of the office action mailed on June 2, 2006 and restated below.

Applicant Claims

Applicant recites a method of treating headache comprising administering to a subject in need of treatment an effective amount of loxapine, loxapine prodrugs, or pharmaceutically acceptable salts thereof, wherein the dosage of loxapine is from about 0.3 to about 20 mg, and administration has the property of resulting in maximal loxapine serum concentration within 15 (claim 13) or 30 (claim 12) minutes of delivery so as to result in a peak rate of increase in blood levels of at least about 1 ng/ml/minute (claim 14) and/or a loxapine blood level of at least about 5 ng/ml within about 15 minutes of administration (claim 15).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Burns teaches an inhalation device provided with a mechanism to assure patient compliance with a drug dosage regimen (abstract) and that patient non-compliance with

inhalation devices has been recognized as a major medical problem (col. 2, lines 39-40). Burns teaches an inhalation device as well as an actuator/timing controller that operates in conjunction with an inhalation device to prevent both patient under compliance with prescribed dosing and patient abuse or dependence on prescribed medication (col. 1, lines 19-24). Burns also teaches that many drugs, which are traditionally delivered by intravenous, subcutaneous, intramuscular, or intraperitoneal injection, can advantageously be delivered by **aerosol inhalation**. Delivery of a drug to the alveoli in the lung to a point where the drug can pass through the lung mucosa can be accomplished with **an MDI, nebulizer, dry powder inhaler, or like device which operates by a patient inspiring solubilized or micronized drug deep into the lung**. In order for the drug to penetrate deeply in the lung, the particles containing the drug should be on the order of a few microns (0.2 to 20) in size. Aerosol delivery is particularly advantageous because first-pass metabolism of the drug by the liver and kidneys is avoided. In addition, the objectionable requirement of finding a suitable injection site and piercing the skin with a needle is avoided. Furthermore, a wide variety of systemically active drugs would benefit from aerosol delivery via inhalation, including neuroleptics, psychotropic drugs, and narcotic antagonists, analgesics, etc (col. 5, lines 29-57). In addition, as delivering systemic drugs by aerosol administration gains wider acceptance, there will be increased demands on the safety of inhalation devices. It is expected that with some drugs, relying on proper patient aerosol administration will not be acceptable. For example, with **headache analgesics**, including, **loxapine hydrochloride**, there may be a tendency of some patients to overdose themselves (col. 7, lines 3-5, 10-17, and 27-30). Burns states that his invention is specifically directed to providing inhalation devices, such as MDIs, nebulizers, and dry powder inhalers, with a safety alarm and actuator mechanism which

both aids in assuring that a patient administers in a timely manner a required dose of drug and prevents overdosing a prescribed drug (col. 7, lines 40-45).

The DIH teaches different oral dosages of loxapine for adults of 10 mg twice daily or more as needed to control psychotic symptoms; that the usual dose range is 60-100 mg/day divided in doses taken 2-4 times/day (i.e. single dosages ranging from 15-25 mg); and that dosages greater than 250 mg/day are not recommended. For I.M. administration the recommended dosages are 12.5-50 mg every 4-6 hours or longer as needed and change to oral therapy as soon as possible (pg 555 of DIH).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Burns lacks the teaching of loxapine dosages. This deficiency is cured by the teachings of the DIH.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been apparent to a person of ordinary skill in the art at the time of the instant invention that one could utilize Burn's inhalation device to deliver loxapine hydrochloride in the practice of a method of treating headache, because loxapine hydrochloride is a known headache analgesic. A skilled artisan would have been motivated to deliver loxapine hydrochloride to treat headache pain (including migraine pain), because this use of loxapine hydrochloride (LoxHCl) is taught by Burns. A skilled artisan would have been further motivated

to select LoxHCl because it is expected that there may be a tendency of some patients to overdose themselves with CNS-affecting drugs, including LoxHCl; and because Burn's device is designed to administer drugs via the inhalation administration of aerosols while assuring proper dosing and preventing overdosing. Regarding the distinction between different types of headache pain, it would have been obvious to a skilled artisan that LoxHCl would be useful in the treatment of these different kinds of headaches/migraines, because it is a known headache analgesic. It is art recognized that analgesics relieve pain.

It would have been obvious to a person of ordinary skill in the art at the time of the instant application to combine the teachings of Burns and the DIH, because the DIH is a well-known reference for commercially available therapeutic agents. Regarding the dosages taught by the DIH, it would have been apparent to a skilled artisan that the dosages required for inhalation administration would be lower than those for oral administration, because via inhalation administration the disadvantage of first-pass metabolism of the drug by the liver and kidneys is avoided (Burns). Therefore, a lower amount of drug would be needed if administered by inhalation. The skilled artisan would utilize the teachings of the DIH regarding the oral doses as a maximum starting point from which to undertake routine optimization of dosage amounts as practiced in the art. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references, because Burns teaches the inhalation administration of LoxHCl as a headache analgesic and the DIH provides the skilled artisan with guidance as to adverse reactions, overdose/toxicology, dosage recommendations, drug interactions, pharmacodynamics of loxapine needed to effectively and safely administer said drug. Regarding the properties associated with inhalation administration, such as systemic

delivery of drug and rapid attainment of maximal loxapine serum concentrations in specific periods of time, it would have been apparent to a skilled artisan at the time of the instant invention that these properties are characteristic of inhalation administration, as the Applicant admits on page 13, paragraph [0041], of the instant specification.

Response to Arguments

Applicant's arguments filed November 9, 2009 have been fully considered but they are not persuasive. Applicants' traversal arguments of the above rejection under 35 U.S.C. §103(a) are: (1) Burns allegedly does not teach loxapine hydrochloride for the treatment of headache and (2) Applicants believe the Examiner has misinterpreted the teachings of Burns.

The Examiner respectfully disagrees with Applicants traversal arguments. Regarding (1), this argument was previously rebutted in the office action mailed on 2/15/07 and the Office's position is unchanged. The passage from Burns (i.e. col. 7, lines 12-19), which Applicants dispute teaches that loxapine hydrochloride is recognized as a headache analgesic is displayed below:

> be acceptable. For example, with neuroleptics, psychotropics, narcotic antagonists, other central nervous system (CNS) drugs and headache analgesics, such as prochlorperazine, fluphenazine hydrochloride, chlorpromazine, trifluperazine hydrochloride, thioridazine hydrochloride, loxapine hydrochloride, and haloperidol decanoate, anxiolytics such as alprazolam, busiprone and diazepam; antidepressants such as amitriptyline,

The plain meaning of the words utilized by Burns is that loxapine hydrochloride is a headache analgesic. The phrase, "such as," conventionally introduces exemplary species of a given group. In this case, the comma after the words "headache analgesics" followed by the

phrase "such as" clearly introduces a short list of drugs recognized as headache analgesics. Applicants' argument is unpersuasive.

Regarding (2), the Examiner and Applicants are at an impasse regarding the teachings of Burns. The instant application appears to be ripe for appeal. The instant rejection is maintained, because Applicants arguments are unpersuasive for the reasons stated above.

Claims 16-17 and 19-20 **remain rejected** under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) in view of Drug Information Handbook, 2nd edition (Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 554-555) ("DIH"), as applied above to claims 1, 5-9, 12-15, and 24 and further in view of Nguyen et al. (U.S. Patent No. 7,040,314) for the reasons of record set forth on pages 12-15 of the office action mailed on June 2, 2006 and restated below.

Applicant Claims

Applicant recites a method of treating headache comprising administering to a subject in need of treatment an effective amount of loxapine, loxapine prodrugs, or pharmaceutically acceptable salts thereof, wherein loxapine or pharmaceutically acceptable salt/prodrug thereof is administered via inhalation using a rapid-heating delivery article or a thin-film drug delivery article (claim 16), wherein said compound is vaporized and condensed to provide at least 50% recovery of said compound in an aerosol containing less than about 5% w/w degradation products.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Burns have been set forth above. Nguyen teaches an aerosol generating device that generates an aerosol by passing liquid aerosol formulation through a flow passage heated to convert the liquid into a vapor, which is mixed with air to form an aerosol, wherein said device can be incorporated in a hand held inhaler. In some embodiments, particles of the aerosol consist essentially of the second component. The aerosol can be delivered to a targeted portion of the lung using the inhaler (abstract). The liquid aerosol formulations include at least one high volatility carrier, preferably a liquid solvent, and a second component, which is a solute dissolved in the liquid carrier, including any suitable medicament that may be delivered to a patient by an aerosol. Suitable medicaments include **analgesics and anxiolytics (e.g. loxapine)** (col. 3, lines 49-52; col. 4, lines 58-67; col. 5, line 26, and claims 18-20). Nguyen teaches that the aerosol-generating device preferably generates aerosols in which 95% of the aerosol particles (aerosol droplets) have a **size between 0.5 microns to about 2.5 microns**, and that the aerosol may contain particles with sizes less than 0.1 microns (col. 15, lines 20-25). In Example 1 and Figure 7, Nguyen teaches that the aerosols generated from a 1% albuterol ethanolic solution by the invented device had an **average MMAD of 0.66 microns**. Nguyen's claims 18, 20, 26, and 28 recite a method of generating an aerosol, wherein the second component is a **medicament**, **the aerosol is a condensation aerosol** and that the aerosol particles having a **MMAD of less than 2.5 microns, respectively**. In Example 7, Nguyen stated that the test results depicted in Fig. 11 demonstrated that the aerosol generating device can be used to prepare budesonide aerosols with **up to 100% recoveries, no observable degradation**, and sufficiently small particle sizes for inhalation, using a carrier, including ethanol.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Burns lacks the teaching of a rapid-heating drug delivery article. This deficiency is cured by the teachings of Nguyen.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Burns and Nguyen, because Burns teaches an inhalation device as well as an actuator/timing controller that operates in conjunction with an inhalation device to prevent both patient under compliance with prescribed dosing and patient abuse or dependence on prescribed medication. The inhalation devices specifically suited for use in combination with Burns teachings include metered-dose inhalers, nebulizers, and dry powder inhalers. Both MDIs and nebulizers are art recognized to deliver aerosols generated from liquid formulations and Nguyen teaches an aerosol generating device wherein formulations comprising a liquid carrier and a medicament are heated to generate aerosols suitable for inhalation administration and characterized by high recovery percentages and very low amounts of degradation products. Therefore, it would have been apparent to a skilled artisan at the time of the instant invention that one could combine the teachings of Burns, suitably used with both MDIs and nebulizers, and have a reasonable expectation of successfully delivering drugs, including loxapine, as aerosols having desirable aerodynamic properties (low MMAD, high recovery, low amount of degradation products) and in such a manner as to improve patient dosage compliance and prevent patient overdose.

Response to Arguments

Applicant's arguments filed November 9, 2009 have been fully considered but they are not persuasive. Applicants' traversal arguments of the above rejection under 35 U.S.C. §103(a) are the same arguments rebutted above with respect to the first rejection under § 103(a). The Office's rebuttal arguments are herein incorporated by reference. The instant rejection is maintained.

Claims 16-18 **remain rejected** under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (U.S. Patent No. 5,284,133) in view of Drug Information Handbook, 2nd edition (Lexi-Comp, Inc.: Cleveland, 1994-1995, pp 554-555) ("DIH") as applied to claims 1, 5-9, 12-15, and 24, and further in view of Rabinowitz et al. (US 2004/0009128) for the reasons of record set forth on pages 15-17 of the office action mailed on June 2, 2006 and restated below.

Applicant Claims

Applicant recites a method of treating headache comprising administering to a subject in need of treatment an effective amount of a loxapine compound, loxapine prodrugs, or pharmaceutically acceptable salts thereof, wherein loxapine or pharmaceutically acceptable salt/prodrug thereof is administered via inhalation using a thin-film drug delivery article (claim 16), wherein said compound is vaporized and condensed to provide at least 50% recovery of said compound in an aerosol containing less than about 5% w/w degradation products (17), and said loxapine compound is coated on a substrate as a thin film having a film thickness between 0.5 and 20 microns (claim 18).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Burns have been set forth above. Rabinowitz discloses a method of delivering an amine drug in an aerosol form is comprising: a) **heating a coating (i.e. a film), which includes an amine drug salt on a substrate contained in a device to a temperature sufficient to volatilize the amine drug** from the coating, b) by said heating, forming an amine drug vapor, and c) during said heating, drawing air through said device, **condensing said vapor to form aerosol particles containing less than 10% degradation products of the compound** (abstract). Rabinowitz also teaches that in more preferred embodiments, the coating of the amine drug salt used has a **thickness between about 0.5 and 20 microns**, and the aerosol particles generated have **a mass median aerodynamic diameter between about 1 and 5 micrometers** [0025]. **Loxapine** is an amine drug, and is identified by Rabinowitz in [0063] as an example of a suitable drug for use in his invention from which an amine salt may be formed. The drug amine salts selected for vaporization preferably have the following characteristics: a molecular weight greater than 200 g/mole and a decomposition index less than 0.15. Typical examples of such preferred drug amine salts that are anxiolytics include **loxapine** [0100]. In Examples 3-4, Rabinowitz teaches general methods of screening drug amines (Example 3) and drug amine salts (Example 4) for aerosolization preferability. In Example 5, Rabinowitz teaches that aerosols formed by his method have an MMAD ranging from 1-3 microns.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Burns lacks the teaching of a thin-film drug delivery article. This deficiency is cured by the teachings of Rabinowitz.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Burns and Rabinowitz, because Burns teaches an inhalation device as well as an actuator/timing controller that operates in conjunction with an inhalation device to prevent both patient under compliance with prescribed dosing and patient abuse or dependence on prescribed medication. A skilled artisan would have been motivated to combine the teachings of Burns and Rabinowitz, because it is expected that with some drugs, relying on proper patient aerosol administration will not be acceptable, such as, **headache analgesics**, including, **loxapine hydrochloride**, which may also suffer from a tendency in some patients to overdose themselves (Burns, col. 7, lines 3-5, 10-17, and 27-30). It would have been apparent to a skilled artisan at the time of the instant invention that one could combine the teachings of Burns, suitable for use with inhalation devices, and have a reasonable expectation of successfully delivering drugs, including loxapine, as aerosols having desirable aerodynamic properties (low MMAD and a low amount of degradation products) and in such a manner as to improve patient dosage compliance and prevent patient overdose. Rabinowitz' device is an inhalation device, therefore, a person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references.

Response to Arguments

Applicant's arguments filed November 9, 2009 have been fully considered but they are not persuasive. Applicants' traversal arguments of the above rejection under 35 U.S.C. §103(a) are the same arguments rebutted above with respect to the first rejection under § 103(a). The

Office's rebuttal arguments are herein incorporated by reference. The instant rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection on the ground of nonstatutory obviousness-type double patenting of claims 1, 16-17, and 19 as being unpatentable over claims 7, 9, 10, 12, and 13 of U.S. Patent No. 6,716,416 (USPN '416) **is maintained** for the reasons of record set forth on pages 17-18 of the office action mailed on June 2, 2006 and because no terminal disclaimer has yet been filed by Applicants.

The provisional rejections on the ground of nonstatutory obviousness-type double patenting of claims 1 and 16-20 (claim 20, only with copending '877) as being unpatentable over (1) claims 12, 15, 16, and 18 of copending Application No. ***10/633,876*** (copending '876) and (2) claims 1 and 7-9 of copending Application No. 10/633,877 (formerly copending '877, now allowed application '877) **are maintained** for the reasons of record set forth on pages 18-19 of the office action mailed on June 2, 2006 and because no terminal disclaimer has yet been filed by Applicants.

Claims 1 and 5-15 **remain provisionally** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of copending Application No. 11/346,548 (copending '548). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are substantially overlapping in scope and/or mutually obvious. Independent claim 1 of the instant application has been described above. Independent claim 1 of copending '548 claims a method of treating headache by the administration of an antipsychotic and dependent claim 15 specifies that suitable antipsychotics for the treatment of headache include loxapine. . The claims of copending '548 do not mention any specific dosages, however, it is well within the capability of the ordinary skilled artisan to determine a therapeutically effective dose of a given drug, and thus, this deficiency is considered an obvious modification. Regarding the properties recited in claims 13-15 of the instant application, these are considered to result necessarily from the inhalation administration of loxapine. Therefore, upon the inhalation administration of loxapine, such as is claimed in claim 15 of copending '763, the properties claimed in claims 13-15 of the instant application would result.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments for Above-Cited Obviousness-Type Double Patenting Rejections

Applicants have stated their intention to file terminal disclaimers upon the identification of allowable subject matter. Because Applicants have not filed any terminal disclaimers the above-cited obviousness-type double patenting rejections are maintained.

Conclusion

Claims 1, 5-9, 12-20, and 24 are rejected. Claims 21-23 are withdrawn from consideration. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner is on a flexible schedule, but can normally be reached on M-F ~10am~5:30 pm, and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.H.A.-A.
Patent Examiner
Technology Center 1600

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616